



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,451	12/20/2001	Jesper Z. Haeggstrom	PVZ-006US	4167
959	7590	07/14/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			ODELL, LINDSAY T	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,451

Applicant(s)

HAEGGSTROM ET AL.

Examiner

Lindsay Odell

Art Unit

1656

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

22

DETAILED ACTION

Application Status

1. In response to the previous Office action, a notice of non-compliance with the sequence rules (mailed on July 1, 2004), Applicants filed a response received on December 28, 2004.

Claims 1-35 are pending in this instant Office action.

Sequence Compliance

2. The Office action mailed on July 1, 2004, asserted that the instant application was not in compliance with the sequence rules because the pending claims and Tables 5-7 contain amino acid sequences that contain 4 or more amino acids without the appropriate sequence listing identification. In the response filed on December 28, 2004 Applicants assert that Tables 5-7 do not require a sequence listing because the tables do not contain sequences of four or more amino acids, but a single amino acids position that can be mutated to various different amino acids. The Examiner agrees with Applicant that the sequences in Tables 5-7 of the instant application do not require a sequence listing; however, Table 9, which is referred to in the pending claims, contains a linear amino acid sequence disclosed as part of the coordinate table without SEQ ID NO identification.

If the noted sequence in Table 9 is in the sequence listing as filed, Applicants must amend the specification to identify the sequence appropriately by SEQ ID NO. If the noted sequence is not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment

Art Unit: 1656

directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 9-10 and 35, drawn to isolated proteins comprising at least a subsequence of the amino acid sequence of LTA₄ hydrolase as disclosed in Table 9.

Group II, claim(s) 6-8 and 25, drawn to compounds that are complementary to the LTA₄ hydrolase described in Table 9.

Group III, claim(s) 11-15, drawn to methods of using the parameter of the protein described in Table 9 (LTA₄ hydrolase) in drug design.

Group IV, claim(s) 11-15, drawn to methods of using the parameters of the compound complementary to the protein described in Table 9 (LTA₄ hydrolase) in drug design.

Group V, claim(s) 16-18, drawn to methods for screening LTA₄ hydrolase analogues.

Group VI, claim(s) 19-20, 30-31 and 35, drawn to analogues of LTA₄ hydrolase.

Group VII, claim(s) 21-24, drawn to methods of screening compounds that are complementary to LTA₄ hydrolase described by Table 9.

Group VIII, claim(s) 26-27, drawn to methods of engineering a protein that is an analogue of LTA₄ hydrolase.

Art Unit: 1656

Group IX, claim(s) 28, drawn to processes of purifying an LTA₄ hydrolase as set forth in Table 9.

Group X, claim(s) 28, drawn to processes of purifying an LTA₄ hydrolase analogue.

Group XI, claim(s) 29, drawn to methods of crystallization of an LTA₄ hydrolase.

Group XII, claim(s) 32-33, drawn to nucleic acids encoding LTA₄ hydrolase analogues.

Group XIII, claim(s) 34, drawn to use of LTA₄ hydrolase analogues in the preparation of LTB₄ or other metabolites in the leukotriene cascade.

4. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The isolated protein that has at least a subsequence of an LTA₄ hydrolase and has the 3-D form essentially disclosed in Table 9 is the technical feature of the first Group. The form described in Table 9 is that of human LTA₄ hydrolase. Minami *et al.* (1988; see PTO-892) teach the purification of human LTA₄ hydrolase (see abstract and page 280, column 1). The human LTA₄ hydrolase purified by Minami *et al.* (1988) has an amino acid sequence which is identical to that in Table 9 of the instant application (see Minami *et al.* 1987; PTO-892). The three-dimensional form of a protein is an inherent property that directly related to its amino acid sequence. Hence, the LTA₄ hydrolase taught by Minami *et al.* has both a subsequence of an LTA₄ hydrolase and the 3-D form essentially disclosed in Table 9. Thus, the technical feature of Group I is not a special technical feature because it does not define a contribution that the Group makes over the prior art. Without a special technical feature, the pending claims are restricted according to their substance as different products (Groups I, II, VI, XII and XIII), and their different categories (Groups III-V and VII-XI, method claims).

Requirement for an Election of Species

5. This application contains claims directed to three species of the generic invention VII. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The three species are as follows:

- a) the general metallohydrolase inhibitor selected in claim 22;
- b) the epoxide hydrolase inhibitor selected in claim 23;
- c) the antagonist of an LTB₄ receptor selected in claim 24.

The following claim is generic: 21.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species of each of claims 22-24 have different functions and are, thus, also expected to have different structures. The technical feature of each of claims 22-24 is different because the compound selected in each claim has distinct functional and structural characteristics. Therefore, the species of claims 22-24 do not share the same or corresponding special technical feature because they have different technical features.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Art Unit: 1656

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-5:30.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.
July 11, 2005


KATHLEEN KERR, PH.D.
PRIMARY EXAMINER
SPE